



# **Department of Veterans Affairs Office of Inspector General**

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## **Healthcare Inspection**

### **Alleged Failure to Obtain Informed Consent and Provide Appropriate Dental Care Minneapolis VA Health Care System Minneapolis, MN**

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## **Executive Summary**

The VA Office of Inspector General (OIG), Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding a failure to obtain informed consent, communicate the plan of care to family and non-VA nursing home (NH) staff, and provide appropriate care after a dental procedure at the Minneapolis VA Health Care System outpatient dental clinic.

We did not substantiate that the provider failed to obtain informed consent prior to extracting multiple teeth. The provider determined that the patient had decision-making capacity and was able to participate in the informed consent process on the day of the oral surgery procedure.

We substantiated that family and NH staff were not aware of the planned extractions. They were notified about an upcoming dental clinic appointment but not that extractions were scheduled. Although not fully effective, communication did occur between the facility and the NH before and after the extractions. Prior to our arrival, the facility had taken steps to improve the content and flow of information between NHs and facility clinics. The facility subsequently established plans for additional improvement.

We did not substantiate that the VA failed to provide appropriate post-extraction care. The NH staff was able to control the bleeding and provide adequate pain relief in the postoperative period.

We made no recommendations.



**DEPARTMENT OF VETERANS AFFAIRS**  
**Office of Inspector General**  
**Washington, DC 20420**

**TO:** Director, Midwest Health Care Network (10N23)

**SUBJECT:** Healthcare Inspection – Alleged Failure to Obtain Informed Consent, and Provide Appropriate Dental Care, Minneapolis VA Health Care System

## **Purpose**

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) conducted an evaluation in response to allegations of a failure to obtain informed consent, communicate the plan of care, and provide appropriate care after a dental procedure at the Minneapolis VA Health Care System outpatient dental clinic. The purpose of this inspection was to determine the validity of the allegations.

## **Background**

The Minneapolis VA Health Care System (facility), part of Veterans Integrated Service Network (VISN) 23, is a tertiary care facility that provides dental, extended care and rehabilitation, mental health, pharmacy, primary care, radiology, recreation therapy, specialty care, spinal cord injury and women's health services. The facility is designated one of the five Polytrauma VA Medical Centers. The facility provides long-term care in community nursing homes under the Veterans Millennium Health Care and Benefits Act<sup>1</sup> for approximately 180 veterans each month.

In the VA system, the process for obtaining informed consent is prescribed in VHA Handbook 1004.01, Informed Consent for Clinical Treatment and Procedures, 2009. The process includes the determination of the patient's decision-making capacity, discussion with the patient concerning the risks, benefits and alternatives to the proposed treatment in language that the patient can understand, and the documentation of the process.

Patients are presumed to have decision-making capacity except in a few circumstances--when an appropriate clinical evaluation determines that the patient lacks decision-making capacity, the patient is a minor, or the patient has been ruled incompetent by a court of law. The practitioner must perform (or obtain) and document

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<sup>1</sup> Also known as the "mill bill," the Millennium Health Care and Benefits Act was passed in 1999 to enhance medical care benefits to eligible veterans.

a clinical assessment of decision-making capacity for any patient suspected of lacking decision-making capacity.

In September 2011, an elderly veteran patient with a diagnosis of dementia who resides in a community nursing home (NH) was scheduled for extraction of multiple teeth at the facility's dental clinic. The patient signed an informed consent document on the day of the procedure and returned to the NH a few hours after the procedure. A confidential complainant alleged that the patient was not able to fully understand what was said to him, that the nursing home staff and the patient's family were unaware of the planned extractions, and that the post-extraction care was inadequate.

## Scope and Methodology

We conducted a site visit to the facility and the community NH, and interviewed the complainant and facility and NH staff. We examined the patient's VA and NH medical records, including Advance Directives and Power of Attorney documents. We also reviewed local policies and peer reviews and researched the literature concerning decision-making capacity assessments.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

## Case Summary

The patient is a widowed male veteran in his 90s who suffered a cerebrovascular accident (stroke) in 2009. He also has a history of dementia, diabetes, macular degeneration, pacemaker implantation, chronic obstructive pulmonary disease, osteoarthritis, bilateral total knee replacements, and spinal stenosis with chronic back pain.

Prior to June 2009, the patient's care was co-managed by a VA primary care physician at the St. Cloud VAMC and a private physician. After his stroke in 2009, he was unable to continue living alone and was placed in a NH close to the St. Cloud VA. In August 2009, he was transferred to a NH in the Minneapolis area to be closer to family.

Under the contract arrangement with the Minneapolis area community NH, the NH provided all primary care services for the patient. Therefore, the patient was not assigned a primary care practitioner at the facility. He did, however, continue to receive specialty services, including dental care, at the facility.

In August 2011, NH staff arranged for a facility dental clinic appointment. According to NH records, the patient had recovered from speech deficits related to the stroke but continued to have some cognitive and memory impairments. The staff noticed some pain behaviors that appeared to be related to the patient's front teeth. Facility dental staff agreed to examine the patient on an emergent basis.

The patient was seen in the dental clinic on two occasions in August. The dental providers were initially unable to isolate the tooth at issue and contacted the NH staff for

clarification. Their examination revealed widespread decay with multiple caries. They recommended extraction of several teeth and made arrangements for oral surgery in September 2011. A letter of notification of a dental clinic appointment in September was mailed to the family and to the NH the day after the patient's second August examination. The letter did not contain details about the proposed plan for the September visit.

The facility provides Client Assisted Services (CAS) for patients who have physical, cognitive or psychological deficits that make it difficult to independently navigate to and from outpatient appointments. The subject patient qualified for CAS and transport was arranged through CAS for the September appointment.

An oral surgeon interviewed the patient prior to the extractions on the morning of the procedure. The oral surgeon determined that the patient had decision-making capacity and explained the risks, benefits, and alternatives of the extractions. The patient signed an informed consent document.

The oral surgeon removed 4 teeth. Because the patient was on aspirin and clopidogrel,<sup>2</sup> the oral surgeon placed gelatin sponges in the extraction sites and sutured the gums closed. According to the facility medical record, the oral surgeon provided the patient with oral and written discharge instructions for post-extraction care and released the patient to the CAS transport.

When the patient returned to the NH, he had some bleeding and oral discomfort. The bleeding was addressed with gauze pads and the discomfort was treated with pain medication. The patient recovered enough from the extractions to attend an ophthalmology appointment at the facility's eye clinic the next day and a family wedding three days later.

## **Inspection Results**

The complainant alleged that the patient was not able to understand what was said to him, that the family and NH staff were unaware of the planned extractions, and that post dental procedure care was inadequate.

### **Issue 1: Failure to Obtain Informed Consent**

We did not substantiate the allegation that the oral surgeon failed to obtain proper informed consent.

In order to obtain informed consent, the provider must first assess the patient's decision-making capacity. According to VHA Handbook 1004.01, assessing decision-making capacity is a clinical determination that a patient has the requisite capacities to make a medical decision. As outlined in the Handbook:

There are four major components to decision-making capacity: understanding appreciating, formulating, and communicating. The

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<sup>2</sup> Aspirin and clopidogrel are medications that prevent blood clots.

first two components represent the patient's ability to understand and appreciate the nature and expected consequences of each health care decision. This includes understanding the known benefits and risks of the recommended treatment options, as well as any reasonable alternative options including no treatment. The latter two components represent the ability to formulate a judgment and communicate a clear decision concerning health care.

We interviewed multiple staff members and providers about the patient's ability to understand, to make choices about activities of daily living, to comprehend verbal instructions, and to voice or otherwise communicate his understanding of his choices. We also reviewed literature on providers' assessments of decision-making capacity.

The NH staff reported that the patient was able to make choices about activities of daily living, could follow directions, and seemed to understand his circumstances. He was, however, very forgetful and could become confused about dates and time. The dental clinic staff reported that the patient seemed to understand and agree to the plan that they proposed.

We found no guidelines in the medical literature that specify how decision-making capacity should be assessed in elderly persons with dementia. It is generally accepted, however, that decision-making capacity can fluctuate and may be appropriate for simple decisions but not for more complex decisions. For example, a patient may not be able to manage his/her finances but can decide what clothes to wear or what to eat. Assessments of decision-making capacity need to be conducted for each proposed intervention.

Although the oral surgeon was not familiar with the patient, the patient's NH diagnosis list included dementia and a cerebrovascular accident. In addition, the patient was escorted to his September dental appointment by CAS staff, which signifies the need for assistance in navigating to and from outpatient appointments. Finally, notes from the August dental clinic visits indicated that the dentist planned to discuss the proposed extractions with a family member. In summary, multiple indicators of a potential problem in decision-making were present.

The oral surgeon reported to us that he recognized that the patient was at risk for impaired decision-making capacity and outlined questions that he generally asks patients to determine capacity. The iMedConsent™<sup>3</sup> form used for documenting informed consent in the VA system requires a "yes/no" statement about the patient's decision making capacity. After an evaluation and discussion with the patient, the oral surgeon documented on the iMed form that the patient had decision making capacity for the extraction procedure.

When the provider determines that the patient has decision-making capacity, the provider is not obligated to consult the patient's health care agent about the proposed procedure. In this instance, we were not able to determine that the patient did not have

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<sup>3</sup> iMedConsent™ is a software package that supports completion of informed consent documents. Its use is described in VHA Handbook 1004.05, IMEDCONSENT™, 2009.

decision-making capacity on the day of the extraction procedure. The record shows that the patient had decision-making capacity, the iMed consent form listed the risks, benefits, and alternatives for the extraction procedure, and the patient signed the document.

## **Issue 2: Failure to Communicate the Plan of Care to Family and NH staff**

We substantiated the allegation that the family and NH staff were unaware of the planned extractions. However, the family and NH staff were aware of the planned dental clinic visit in September. The patient was seen in August and plans were made for extractions in September. Two communications about the September visit were conveyed to the family and/or NH staff.

The first communication was a letter of notification from the dental clinic to both the family and the NH that the patient was scheduled for a dental clinic appointment in September. The notification letter, however, did not include specific details about the visit and did not mention the proposed extractions.

The second communication was a document entitled "Physician Visit Record" which this NH sends with the patient to the provider along with a list of medications and diagnoses. The clinician who treats the patient completes the bottom section of the Physician Visit Record with details of the visit, results of lab work, new orders, new treatments, and date of return visit. We found Physician Visit Record documents in the NH records for the August visits but the documents did not include information about planned extractions.

Because the dentists who examined the patient in August and the oral surgeon who performed the extractions in September thought that the patient had decision-making capacity, they did not consider looking for or contacting a health care agent to discuss the plan of care. According to family and NH staff, the patient did not inform them about the planned extractions.

Notwithstanding the determination in September that the patient was able to make his own decision, the dentists who examined the patient in August told us that they had planned to call a family member in order to discuss the extent of the patient's dental decay. They obtained the family contact information from the nursing home but ultimately did not make the call.

Prior to our visit, the facility had identified potential gaps in communication between VA clinic providers and non-VA providers and planned to require that a copy of a visit's progress note be included with documents returned to the NH with the patient. Had a copy of this patient's August VA progress note been returned with the patient to the NH, the NH staff would have been aware of the proposed extractions.

We also investigated communications between the NH and dental providers after the extractions. Patients who undergo oral surgery at the facility dental clinic are provided pre-printed discharge instructions entitled "Care After Oral Surgery" to assist them with



their home care. The instructions include information about what to expect after the surgery, appropriate activity, appropriate diet, and what to do if pain, bleeding or swelling occurs or becomes excessive. Several contact numbers are listed on the second page of the two-page document.

According to the facility's electronic medical record, the oral surgeon provided both oral and written instructions (Care After Oral Surgery document) to the patient along with a gauze pack dressing and orders for pain medications. According to the NH staff, the patient returned to the NH via the CAS transport without discharge instructions.

The patient did return, however, with the NH's Physician Visit Record document. The oral surgeon had listed the teeth extracted as well as his contact number and an order for two pain medications.

NH staff reported that they had a question about the post-extraction plan of care and attempted to call the contact number that was provided in the September Physician Visit Record but was unsuccessful in reaching the oral surgeon. We were unable to confirm whether written discharge instructions were sent back to the NH with the patient or whether a call was made to the dental clinic. NH staff, however, had experience in taking care of post-oral surgery patients and were able to institute appropriate measures to control the patient's pain and bleeding.

We found gaps in the information available to providers in the facility electronic medical record. The patient's contact information had not been updated following the patient's transfer from St. Cloud to Minneapolis; his spouse was listed as his next of kin although she had died several years earlier. Additionally, the NH had a copy of the patient's most current Advance Directive with appointment of a health care agent, but facility staff was unaware that the patient had a designated health care agent.

In VHA facilities, the patient's PCP manages all aspects of the veteran's care, including the updating of clinical and personal information. Gaps in this patient's contact and health care agent information may have been attributable to the contractual arrangement between the NH and the VA. Pursuant to the contract, the NH provides primary care and the patient is not assigned a VA PCP. Facility leaders told us that they were addressing this information gap by revising the evaluations completed by the nurses and social workers who make monthly visits to community NHs. In addition to evaluating the care of veterans who reside in NHs, visiting staff can ensure that key information is updated in the facility's electronic medical record.

### **Issue 3: Failure to Provide Adequate Post Dental Procedure Care**

We did not substantiate that the VA facility failed to provide appropriate post dental procedure care.

The patient was on two medications that interfered with blood clotting. The oral surgeon took measures to control post-operative bleeding by using gelatin sponges and sutures. He prescribed two pain medications. He also documented that he provided the patient with oral and written instructions stating that oozing of blood may occur for a few hours,

that moderate bleeding could be controlled with gauze held in place, and to call if excessive bleeding occurred.

The patient did have some post-operative bleeding that was controlled with gauze pads and pressure. According to his NH primary care provider, the bleeding was not excessive and did not result in symptoms that would have required intervention on her part. His oral and facial discomfort was treated with the prescribed pain medications.

## Conclusions

We did not substantiate that the provider failed to obtain informed consent prior to extracting multiple teeth. The provider determined that the patient had decision-making capacity and was able to participate in the informed consent process on the day of the oral surgery procedure.

We substantiated that the family and NH staff were not aware of the planned extractions. They were notified of an upcoming dental clinic appointment but not informed that extractions were scheduled. Although not fully effective, communication did occur between the facility and the NH before and after the extractions. Prior to our arrival, the facility had taken steps to improve the content and flow of information between NHs and facility clinics. The facility subsequently established plans for additional improvement.

We did not substantiate that the VA failed to provide appropriate post-extraction care. The NH staff was able to control the bleeding and provide adequate pain relief in the postoperative period.

We made no recommendations.

## Comments

The Veterans Integrated Service Network and Medical Center Directors concurred with the report. No further action is required.



JOHN D. DAIGH, JR., M.D.  
Assistant Inspector General for  
Healthcare Inspections

## VISN Director Comments

### Department of Veterans Affairs

### Memorandum

**Date:** March 7, 2012

**From:** Director, Midwest Health Care Network (10N23)

**Subject:** **Healthcare Inspection – Alleged Failure to Obtain Informed Consent, Communicate the Plan of Care, and Provide Appropriate Care after a Dental Procedure, Minneapolis VA Health Care System**

**To:** Director, Washington DC Office of Healthcare Inspections (54DC)

**Thru:** Director, Management Review Service (10B5)

1. This is to acknowledge receipt and review of the draft Healthcare Inspection report for the Minneapolis VA Health Care System.
2. We appreciate the opportunity to comment and concur with the draft document.

*(original signed by:)*

Janet P. Murphy, BA, MBA

Director, Midwest Health Care Network (10N23)

## Facility Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** March 7, 2012

**From:** Director, Minneapolis VA Health Care System (618/00)

**Subject:** Healthcare Inspection – Alleged Failure to Obtain Informed Consent, Communicate the Plan of Care, and Provide Appropriate Care after a Dental Procedure, Minneapolis VA Health Care System

**To:** Director, Midwest Health Care Network (10N23)

This is to acknowledge receipt and review of the draft Healthcare Inspection report for the Minneapolis VAHCS.

The Director and Leadership have reviewed and concur with the OIG findings without recommendations. We will continue with our efforts for additional improvements to increase communication flow between NH and facility clinics.

I appreciate the opportunity to respond the Healthcare Inspection report. Thank you for your assistance.

*(original signed by:)*

Barry D. Sharp, MPS, MBA

Acting Director, Minneapolis VA Health Care System  
(618/00)

## **OIG Contact and Staff Acknowledgments**

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720
Acknowledgments	Randall Snow, JD, Project Leader Kathy Gudgell, RN, JD, Team Leader Jerome Herbers, MD, Medical Consultant Donna Giroux, RN

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